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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,502	10/11/2001	Jerry G. Henslee	5972.US.P7	1118

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/23/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/975,502

Applicant(s)

HENSLEE ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12,15</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-5) in Paper No. 18, received July 9, 2003 is acknowledged. However, applicant did not distinctly and specifically point out the supposed errors in the restriction requirement.
2. Claims 1-8 are pending.
Claims 6-8, drawn to non-elected inventions are withdrawn from examination.
Claim 2 has been amended.
Claims 6-8 have been added.
Claims 1-5 are examined on the merits.

Priority

3. It is noted that the Applicants desire priority under 35 U.S.C. 120 based upon several previously filed applications. Several of the parent applications (i.e. 09/467,602) have become patents. The expression "now Patent No. ____" should follow the filing date of the parent application on the first line of the specification.
4. The Examiner has reviewed the U.S. Applications from which priority is claimed. The limitations of all the breast cancer markers, mammaglobin (SEQ ID NO: 5), BU101 (SEQ ID NO: 6) and BS106 (SEQ ID NO: 8) have only been disclosed in the instant application. Accordingly, claims 1, 2 and 5 are afforded the priority date of October 11,

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2001. One claim is afforded one priority date, which represents the date at which all limitations are disclosed.

Claim Objections

5. Claim 4 (c) is objected to because of the following informality: the recitation "thepresence" should read "the presence". Correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 2 and 5 are vague and indefinite because they do not reference the breast cancer markers/proteins with identifying SEQ ID numbers. Applicants can obviate this rejection by amending the claims to recite the proteins' SEQ ID number.

b. Claims 1 and 2 are vague and indefinite because they recite incomplete method steps. While it is clear that that there is the detection of at least one polypeptide in a sample indicative of breast cancer the claims do not provide how that one polypeptide is detected. It is not clear what is the diagnostic tool used in the assay.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/21331 (May 22, 1998). The WO document discloses Applicants' mammaglobin (SEQ ID NO: 5) and BU101 (SEQ ID NO: 6) polypeptides, which are the same as human steroid-binding protein, hSBP2 (sequence 3) and HSBP1 (sequence 1), respectively within the said document, see attached database sheets. The abstracts listed on the database sheet state that hSBP1 and hSBP2 are used in methods of diagnosis and monitoring breast cancer. These molecules are both useful breast cancer markers "[a]ntibodies are used as diagnostic reagents in standard immunoassays for hSBP, see last line of database sheet abstract.

On page 22, lines 1-4 it is disclosed detection of hSBP expression can be examined in breast tissue in situ or in pathology sections and alternatively in blood, serum or plasma. Further disclosed are diagnostic assays using hSBP specific antibodies wherein "[t]he amount of standard complex formation can be quantified by comparing detection levels associated with known quantities of hSBP with detection

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levels associated with both control and disease samples from biopsied tissues", see page 24, lines 4-28. "Deviation between standard and subject values establishes the presence of disease state", see page 24, line 28.

10. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent application publication US 2003/0059432 (filed July 13, 2001). The U.S. patent application publication discloses Applicants' mammaglobin (SEQ ID NO: 5) and BU101 (SEQ ID NO: 6) polypeptides, which are the same as lipophilin-like protein, mammaglobin (sequence 1) and lipophilin B (sequence 2), respectively within the said publication see attached database sheets. The disclosed diagnostic method assays for the presence or absence of a cancer (i.e. breast) in a patient which may comprise two antibodies using a biological sample from a patient, see page 1, bridging paragraph of section 0007 and page 2, sections 0017, 0018 and 0025.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

0196.

ALANA HARRIS
PATENT EXAMINER



Alana M. Harris, Ph.D.
September 17, 2003